No. 01-1399

Supreme Court, U.S.
FILED
APR 18 2002
OFFICE OF THE CLERK

In The

Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL. JACK OBEYDEAN SWAFFORD, also known as Dean J. Swafford,

Petitioner,

v.

BORGESS MEDICAL CENTER, a nonprofit Michigan corporation; ADVANCED VASCULAR SURGERY, P.C., a Michigan professional corporation; JAIN KRISHNA, M.D.; JOHN MUNN, M.D.; EUGENE SIMONI, M.D.; JOHN T. COLLINS, JR., M.D. AND RANDY SMEJKAL, M.D., P.C., a Michigan corporation; JOHN T. COLLINS, JR., M.D.; RANDY SMEJKAL, M.D.; JAMES MCLAREN, M.D.; HEALTHCARE MIDWEST GENERAL & SURGEONS, also known as Healthcare Midwest, P.C., a Michigan corporation; MARK TAGETT, M.D.; PHILIP BOROZAN, M.D.; SOLOMON K. SAMUELS, M.D., P.C., a Michigan corporation; SOLOMON K. SAMUELS; PADRAIC CARMODY, M.D.; VASCULAR SPECIALISTS, P.C.; a Michigan corporation; KARIM ABEDEL ABUSHMAIES, M.D.; M. ABIDUR RAHMAN, M.D., jointly and severally,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Sixth Circuit

OPPOSITION BRIEF OF RESPONDENTS HEALTHCARE MIDWEST, P.C., MARK TAGETT, M.D., AND PHILIP BOROZAN, M.D.

David A. French
Counsel of Record
Sonal Hope Mithani
Miller, Canfield, Paddock and Stone, P.L.C.
101 North Main Street
Seventh Floor
Ann Arbor, Michigan 48103-1400
(734) 663-2445

Attorneys for Respondents Philip Borozan, M.D., Mark Tagett, M.D., and Healthcare Midwest, P.C.

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

Whether a writ of certiorari is necessary to review the decision of the United States Court of Appeals for the Sixth Circuit to affirm the United States District Court for the Western District of Michigan's opinion granting the Respondents summary judgment when:

(1) The Petitioner conceded that there was no regulation or law requiring the Respondents to perform venous ultrasound studies in the manner advocated by the Petitioner; and

(2) The other circuits addressing the issue agree that in the absence of a controlling regulation or law, a dispute over how best to perform a test or study is not actionable.

PARTIES TO THE PROCEEDING

In addition to the parties identified by the Petitioner, the United States of America is an interested party in this case. The Petitioner brought his False Claims Act claims against the Respondents as a private citizen or "relator." The United States, through the Department of Justice, had an opportunity to intervene in this action. In this case, the United States declined to intervene. Moreover, the United States – acting as Amicus Curiae – filed a brief supporting affirmation of the District Court's decision.

CORPORATE DISCLOSURE STATEMENT

Respondents Philip Borozan, M.D. and Mark Tagett, M.D. are individuals who are not required to submit a corporate disclosure statement. Respondent Healthcare Midwest, P.C. is not the subsidiary or affiliate of a publicly-owned corporation. Nor is there a publicly-owned corporation not a party to the appeal that has a financial interest in the outcome.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

PARTIES TO THE PROCEEDING ii

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES iv

COUNTER-STATEMENT OF THE CASE 1

REASONS FOR DENYING THE WRIT 4

I. THE LOWER COURTS' DECISIONS ARE CONSISTENT WITH THE DEVELOPED RULE OF LAW THROUGHOUT THE CIRCUITS AND THUS FAIL TO RAISE AN IMPORTANT QUESTION FOR THIS COURT 5

II. THE DECISION GRANTING SUMMARY JUDGMENT IS NOT UNUSUAL GIVEN THE ABSENCE OF CONTROLLING LAW AND THE UNCONTROVERTED EVIDENCE THAT THE PHYSICIANS PROVIDE A SERVICE OF VALUE 9

CONCLUSION 12

TABLE OF AUTHORITIES

Page

CASES

Bickel v. Korean Air Lines Co., Ltd., 96 F.3d 151 (6th Cir. 1996) 11

Hagood v. Sonoma County Water Agency, 81 F.3d 1465 (9th Cir. 1998)..... 7

Luckey v. Baxter Healthcare Corp., 183 F.3d 730 (7th Cir. 1999) 4, 6, 7, 8

Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001)..... 6, 7, 8

United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 889 (5th Cir. 1997) 7

United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149 (W.D. Mo. 2000).....8, 9

RULES

Sup. Ct. R. 10(a).....5, 10

Sup. Ct. R. 10(c)..... 5

COUNTER-STATEMENT OF THE CASE

This Petition is brought by Jack Obeydean Swafford ("Swafford"), who asserts that Respondents Philip Borozan, M.D., Mark Tagett, M.D., and Healthcare Midwest P.C. (the "Physicians") have committed fraud under the False Claims Act ("FCA"). In his Petition, Swafford argues that the United States District Court for the Western District of Michigan and the United States Court of Appeals for the Sixth Circuit improperly granted and affirmed summary judgment in favor of the Physicians.

At every stage of this case, Swafford has argued that the Physicians have allegedly committed fraud because they have not read or interpreted venous ultrasound studies reported as negative for deep vein thrombosis.[1]

---

[1] A venous ultrasound (or doppler) study consists of two components. (Pet. App. at 39a.) The first is the technical component, during which vascular technicians or registered vascular technologists objectively test four characteristics – spontaneity, augmentation, phasicity, compressibility – of a patient's veins. (*Id.* at 40a.) These tests are objective because the results are binary: i.e., a vein is compressible or not. There is no intermediate result. (*Id.* at 41a.) The technicians report the test results on a worksheet. (*Id.* at 40a.)

The second part of the venous study is the professional component, in which trained physicians read or interpret the findings reported on the technicians' worksheets. (*Id.* at 40a-41a.) The physicians review the test data and integrate that information with any relevant information contained in the patient's file, and any other available or known relevant information in order to make a conclusion about the study (i.e., whether the test is negative or positive for deep vein thrombosis, needs to be repeated, or is negative for deep vein thrombosis but reveals other incidental abnormalities). (*Id.* at 44a-45a.)

Swafford claims that in order to perform a reimbursable "service," (i.e., an "interpretation" or "reading" of the results of a venous ultrasound study), the physicians must have actually viewed the videotapes or photographs (instead of the paper worksheets) produced by the technicians performing the study. According to Swafford, unless the Physicians viewed the videotapes, any billing to the federal government for physician services in connection with negative venous studies is a false claim.

No applicable law or regulation, however, requires the physicians to view a videotape or photograph in connection with their interpretation or reading of the venous studies. Thus, whether the physicians must review a videotape or photograph is really a question of whether the appropriate standard of care has been provided to the patient. As both the District Court and the Court of Appeals ultimately concluded, disputes about whether the provided services fall short of the standard of care are not actionable.

Believing Swafford's claims to be meritless, the Physicians filed a motion to dismiss Swafford's FCA action in September 1999. After denying the motion to dismiss, the District Court ordered limited discovery to determine whether the Physicians provided a service of some value, or did nothing at all before they billed for the reading of the studies. In other words, the District Court, in its discretion, decided that the Petitioner would first be required to find evidence of "falsity" before proceeding with additional discovery.

Upon completion of this limited phase of discovery, the Physicians moved for summary judgment. After

reviewing all the evidence and hearing from both parties, the District Court concluded that Swafford failed to show that there was a genuine issue of material fact with respect to his claims:

> In conclusion, plaintiff's disagreement with the qualitative nature and degree of review necessary for defendant physicians to claim to "interpret" the technical component of a venous ultrasound study and then bill the government for the professional component fails to amount to either a false claim or knowingly false claim under the FCA. . . . Moreover, even were plaintiff to succeed in demonstrating defendants submitted false claims because they did not review the underlying hard copy data from the studies, the record fails to establish that defendants acted either in deliberate indifference or reckless disregard of the truth of the claims.

(February 18, 2000 Opinion ("Op.") at 24 (Pet. App. at 23a-24a).) The District Court particularly noted that Swafford "does not deny . . . that defendant physicians reviewed the materials. . . . " (*Id.* (Pet. App. at 19a).) Concluding that the Physicians did perform a service of value, the District Court granted summary judgment in the Physicians' favor, dismissing Swafford's claims.

Swafford then appealed this decision to the Court of Appeals, which issued a pithy opinion on December 12, 2001 affirming the District Court. (Pet. App. at 27a-29a.) Reviewing the District Court's grant of summary judgment de novo, the Court of Appeals found no error with the District Court's conclusion that Swafford failed to present actionable FCA claims.

REASONS FOR DENYING THE WRIT

Two courts have already examined the issues raised in Swafford's complaint. Both have concluded that summary judgment in favor of the Physicians is appropriate. Despite this, Swafford now requests a writ of certiorari review even though he has failed to show a compelling reason warranting this Court's involvement. Although Swafford offers a number of bases to justify this Court's review (none of which are clearly articulated), his primary arguments appear to be (1) the lower courts failed to consider certain guidelines and the standard of care when it concluded that the Physicians did not make false claims and (2) there were genuine issues of material facts that precluded summary judgment. Swafford is incorrect in his assessment of the lower courts' "errors."

As both lower courts properly concluded, there is no law or regulation requiring the Physicians to review the videotapes of venous ultrasound studies. Nor does Swafford's suggestion that the Physicians have violated the appropriate standard of care create an important question for the Court. The nation's federal courts have repeatedly held that when parties, who agree that a service has been provided, only question whether the service satisfied a standard of care, no FCA claim will lie. *See, e.g., Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 731-33 (7th Cir. 1999) (affirming summary judgment).

In short, the lower courts were correct to grant the Physicians' motion for summary judgment and there is no reason why this decision should be reversed or even reviewed by the Court. Thus, the Respondents respectfully request that the Court deny the Petition.

I. THE LOWER COURTS' DECISIONS ARE CONSISTENT WITH THE DEVELOPED RULE OF LAW THROUGHOUT THE CIRCUITS AND THUS FAIL TO RAISE AN IMPORTANT QUESTION FOR THIS COURT.

Swafford's Petition so confuses and conflates the issues in this case, it is difficult to ascertain what exactly is the important question necessitating this Court's review. Sup. Ct. R. 10(a), (c). Yet, it appears that – among other issues – Swafford disputes the lower courts' conclusion that there was no applicable law or regulation governing the submission of claims for the venous ultrasound studies. (Pet. App. at 12-24.) Swafford apparently forgets that he already conceded this issue in the District Court:

> THE COURT: Mr. Gagleard, this is not that hard a question to answer, and I'm going to try it one last time, and if you won't answer it, then I'm going to assume that there is nothing in the regulation that's provided to the physicians that makes such a requirement. You quote extensively from the Carrier Manual. You quote from cases. I don't see anything that you quote from that Provider Manual that says that they had to look at the still photos or look at the video. Now, I understand you are making arguments about this means that, but I don't see any reference to a portion of the Provider Manual that says that they were required to do what you were requiring [them] to do. Am I right about that or am I wrong?
>
> MR. GAGLEARD: I believe you are accurate. There is nothing that says that the radiologist –

> strike that. *There's nothing that says that you have to look at the video or the photos.*

(November 29, 1999 Summary Judgment Hearing Transcript ("Tr.") at 29-30 (Resp. Br. App. 10-11.) (emphasis added).)

If there is no regulation or guidance requiring the Physicians to do what Swafford claims they should have done, there is no false claim under the FCA. Neighboring circuits concur. *See Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 731-33 (7th Cir. 1999) (affirming summary judgment dismissing FCA claims since none of the federal regulations required the defendant to test blood plasma in the method or manner the plaintiff thought the blood should be tested).

The circuit courts have also held that when parties disagree over the *nature* of the performance of a particular procedure or test (for which a claim for reimbursement is being made), there is no basis for an FCA action.[2] *Id.* at 733 ("All this record reveals is a dispute about whether Baxter's testing protocols could be improved. An affirmative answer to that question would not suggest that Baxter's representations to the United States in the years past were false or fraudulent."); *Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001) ("[D]efendants did not submit impliedly false claims by requesting reimbursement for

---

[2] This Court has not addressed the legal issues presented in this case.

spirometry tests that allegedly were not performed according to the recognized standards of health care.").[3]

These circuits have specifically indicated that "ineffective testing" is not the same as "no testing." *See, e.g., Luckey*, 183 F.3d at 732. Thus, disputes relating to the level of care provided by the provider are not actionable under the FCA. If a defendant physician bills for a test or service which she provides, but in doing so fails to provide the highest level of care advocated by the plaintiff, this does not give rise to a false claim. *See, e.g., Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998) (" . . . [T]he common failings of engineers and other scientists are not culpable under the Act."). Certainly, this makes sense since disputes over the appropriate standard of care concern questions of scientific judgment. If the courts were to allow FCA claims predicated on an inappropriate level of care, then every medical malpractice claim would be subject to FCA liability and the federal government would find itself in the unenviable position of prosecuting these types of claims. *See Mikes*, 274 F.3d at 700.

The record in this case reveals that Swafford does not dispute that the Physicians provided some service: i.e., reading and reviewing the worksheets prepared by the technicians who conducted the venous ultrasound test. (Tr. at 25 (Resp. Br. App. 6).) Thus, Swafford's argument is not whether the Physicians provided a service but rather, whether the Physicians provided "enough" of a

---

[3] *See also Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1998); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 889 (5th Cir. 1997).

service by only reading and interpreting the worksheets, and not the videotapes of the tests.[4] (Tr. at 47 (Resp. Br. App. 27).) Simply put, Swafford argued that the Physicians did not satisfy the purported standard of care for venous ultrasound studies. Relying on *Luckey*, *Mikes*, and other cases, the District Court concluded as a matter of law that Swafford's claims that the Physicians did not do more in reviewing the venous ultrasound studies were not actionable:

> The Court finds the reasoning of these authorities quite persuasive, and concludes plaintiff cannot demonstrate a genuine issue of material fact with respect to false claims under the FCA, even if he can demonstrate defendants' practice failed to conform to the standard of care applicable to the interpretation of venous ultrasounds.

---

[4] Thus, this case is different from *United States v. NHC Healthcare Corp.*, 115 F.Supp.2d 1149 (W.D. Mo. 2000). (Petition at 21-23.) In *NHC*, the plaintiff's claims were brought under the theory that the services provided by the defendant were so severely deficient that essentially no service was provided. The district court noted that "[t]he billing dispute at issue here is not *how* the Defendant turned, bathed, administered drugs to, and fed the two residents in question, but whether the Defendant did these things *at all*." *Id.* at 1155 (emphasis added). As the *NHC* court acknowledged, these circumstances were markedly different from those in *Mikes*, in which it was evident the physicians had provided a service of some medical value. In this case (as in *Mikes*), it is uncontroverted that the Physicians provided a service of value to their patients. (Pet. App. 19a, 38a-47a; Tr. at 25 (Resp. App. Br. 6).)

(Op. at 18 (Pet. App. at 18a-19a).) This finding was affirmed by the Sixth Circuit. (December 12, 2001 Opinion ¶ 1 (Pet. App. at 28a).)

Apart from the inapposite *United States v. NHC Healthcare Corp.*, 115 F. Supp.2d 1149 (W.D. Mo. 2000), discussed *supra* at n.4, Swafford has not cited one case to support his belief that the issues raised in this lawsuit present an important matter in which the various circuits are in conflict. If anything, it appears that the courts addressing this issue (including the district court in *NHC*) would agree with the lower courts' conclusion that Swafford's claims are not viable. Swafford's claims only challenge the Physicians' scientific judgment as to the appropriate level of care. Such disputes do not support an FCA action as a matter of law. This Court should deny the request for writ.

II. THE DECISION GRANTING SUMMARY JUDGMENT IS NOT UNUSUAL GIVEN THE ABSENCE OF CONTROLLING LAW AND THE UNCONTROVERTED EVIDENCE THAT THE PHYSICIANS PROVIDE A SERVICE OF VALUE.

Swafford argues that summary judgment was inappropriate because there were numerous and genuine issues of material facts concerning (1) the law and regulations governing the performance of venous ultrasound studies and (2) the Physicians' intent. However, Swafford never argues or explains why the summary judgment decision was so far departed from the usual course of judicial proceedings that further review is warranted.

Sup. Ct. R. 10(a). This is probably because such an argument would be specious, at best.

Swafford first contends that there are genuine issues of material facts such as whether the Physicians submitted false claims in light of the standard of care, various manuals and regulations. (Pet. at 14-17.) The District Court concluded that *all* of the extraneous materials offered by Swafford are not applicable:

> Given the lack of specific billing regulations concerning venous ultrasounds, the Court is not persuaded by plaintiff's arguments. As a matter of law, the Court concludes plaintiff's position on this issue is insufficient to establish a genuine issue of material fact. Plaintiff concedes HCFA [the Health Care Financing Administration] has not promulgated specific regulations relating to the submission of reimbursement claims for venous ultrasounds. . . . Plaintiff has neither established that compliance with these [other] standards is a prerequisite for reimbursement by Medicare for venous ultrasounds, nor adduced any facts to support an inference that the physicians knew or believed these regulations to be applicable to their submissions.

(Op. at 10-11 (Pet. App. at 11a-12a).) Swafford's Petition fails to explain why the District Court's holding is incorrect. Swafford does not provide any persuasive authority arguing that the various manuals and regulations cited in the Petition are applicable to venous ultrasound studies. Rather, as noted earlier (*supra*, Section I), Swafford admitted that Medicare has not specifically promulgated regulations governing a physician's interpretation of venous

ultrasound studies.[5] When Swafford himself concedes that there are no controlling regulations, a decision granting summary judgment is neither unusual nor suspect.

Swafford next argues that the District Court erred when it concluded that there was no genuine issue of material fact regarding the Physicians' intent. Swafford complains that the District Court applied the wrong standard when it found there was no evidence of intent. Unfortunately for Swafford, he never challenged the scienter standard used by the District Court on appeal; thus, the issue is now waived. *See Bickel v. Korean Air Lines Co., Ltd.*, 96 F.3d 151, 153-54 (6th Cir. 1996) (concluding that appellant waived issue when it failed to raise the issue in its opening brief).

Swafford's contention is also just plain wrong. The District Court specifically articulates in Section IV of its Opinion the very standard Swafford argues for in this case. (February 18, 2000 Opinion at 21 (Pet. App. at 21a) ("To succeed under the FCA, a relator need not demonstrate specific intent to defraud the government."). Using the correct standard, the District Court concluded that the Physicians lacked the requisite level of intent because they believe they are providing a service when they review the technicians' worksheets (Pet. App. 38a-47a), Swafford has already admitted that the Physicians do review and read the worksheets (Tr. at 25 (Resp. Br. App. 6)), and there is no regulation or law requiring the Physicians to do more than this. Swafford fails to provide a

---

[5] *See also* Op. at 9 (Pet. App. at 10a) (*citing* Pl. Orig. Br. at 1, n.4, Dkt. No. 6).

persuasive or compelling reason why this decision of the District Court (and the Sixth Circuit) is so extraordinary that it should be reviewed by this Court. As such, the request for writ must be denied.

CONCLUSION

For the reasons stated above, Respondents Healthcare Midwest, P.C., Mark Tagett, M.D., and Philip Borozan, M.D. respectfully request that this Honorable Court deny the Petition for Writ of Certiorari.

Respectfully submitted,

DAVID A. FRENCH
Counsel of Record
SONAL HOPE MITHANI
MILLER, CANFIELD, PADDOCK AND STONE, P.L.C.
101 North Main Street
Seventh Floor
Ann Arbor, Michigan 48104-1400
(734) 663-2445

Attorneys for Respondents Philip Borozan, M.D., Mark Tagett, M.D., and Healthcare Midwest, P.C.

Dated: April 18, 2002

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA, EX REL. JACK OBEYDEAN SWAFFORD, a/k/a DEAN J. SWAFFORD,

Plaintiffs,

vs. No. 4:97-CV-116

BORGESS MEDICAL CENTER, a nonprofit Michigan corporation, ADVANCED VASCULAR SURGERY, P.C., a Michigan professional corporation, KRISHNA JAIN, M.D., JOHN MUNN, M.D., EUGENE SIMONI, M.D., JOHN T. COLLINS, JR. M.D., and RANDY SMEJKAL, M.D., P.C., a Michigan corporation, JOHN T. COLLINS, JR., M.D., RANDY SMEJKAL, M.D., JAMES McLAREN, M.D., HEALTHCARE MIDWEST GENERAL & VASCULAR SURGEONS, a/k/a HEALTHCARE MIDWEST, P.C., a Michigan corporation, MARK TAGETT, M.D., PHILIP BOROZAN, M.D., SOLOMON K. SAMUELS, M.D., P.C., a Michigan corporation, SOLOMON K. SAMUELS, M.D., PADRAIC CARMODY M.D., KARIM ABEDEL ABUSHMAIES, M.D., and M. ABIDUR RAHMAN, M.D., jointly and severally,

Defendants.
_____/

(Filed Jun. 19, 2000)

DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT
BEFORE THE HONORABLE DAVID W. McKEAGUE
UNITED STATES DISTRICT JUDGE
Lansing, Michigan, November 29, 1999, at about 1:55 P.M.

[2] APPEARANCES:

Michael A. Gagleard
Ishbia & Gagleard, P.C.
251 Merrill Street, Second Floor
Birmingham, MI 48009

On behalf of the Plaintiffs;

Jeffrey D. Smith
Varnum, Riddering, Schmidt & Howlett, L.L.P.
350 East Michigan Avenue, Suite 500
Kalamazoo, MI 49007

On behalf of Defendants Karim Abedel Abushmaies, M.D., M. Abidur Rahman, M.D., Padraic Carmody, M.D., Solomon K. Samuels, M.D., P.C., Solomon K. Samuels, M.D., John T. Collins, Jr., M.D., Randy Smejkal, M.D., James T. McLaren, M.D., Advanced Vascular Surgery, P.C., Krishna M. Jain, M.D., John S. Munn, M.D. and Eugene J. Simoni, M.D.;

Seth Lloyd
Dykema Gossett, P.L.L.C.
400 Renaissance Center
Detroit, MI 48243-1668

On behalf of Defendant Borgess Medical Center;

David A. French
David L. Freedman
Miller, Canfield, Paddock and Stone, P.L.C.
101 North Main Street, 7th Floor
Ann Arbor, MI 48104-1400

On behalf of Defendants Healthcare Midwest, P.C.; Mark Tagett, M.D.; and Philip Borozan, M.D.

Court Reporter: Sharon E. Fox, CSR-3342
315 West Allegan Avenue
Lansing, MI 48933
(517) 484-8083

* * *

[21] Mr. Gagleard.

MR. GAGLEARD: Thank you, Your Honor.

THE COURT: While it's fresh in my mind, let's start with those same questions.

MR. GAGLEARD: Okay.

THE COURT: Do you have any disagreement with what Mr. Smith and Mr. Lloyd have said?

MR. GAGLEARD: Some. I believe that you may have a partial obstruction and you may have one or more of the five factors be negative or be positive and yet have an acute partial blood clot – I'm sorry – a partial obstruction or [22] you may have a total obstruction. This is – this is not one of the processes whereby you would present and there is either a blood clot or there is no blood clot. As a matter of fact, you can have a complete obstruction, you can have a partial obstruction. You can have an acute blood clot or you can have a chronic blood clot. Chronic blood clot is one that's been around for a while, doesn't necessarily require immediate treatment, and is not necessarily a medical emergency.

THE COURT: Well, regardless of whether the positive finding is DVT or something less than that, if there is such a thing –

MR. GAGLEARD: Yes, sir.

THE COURT: – is the procedure that first Mr. Smith and then Mr. French agreed to what you understand happens here? These doctors are asked to come in and read these tests for any number of reasons and they go and they find a work sheet, and maybe it's accompanied by other things and maybe it isn't, and they don't know in advance whether it's going to be positive, negative, or negative with an abnormality.

MR. GAGLEARD: I'd agree with that.

THE COURT: Now, you are contending in this case that they can't bill for a report that they dictate based upon a work sheet that is negative for DVT, correct?

MR. GAGLEARD: That's true.

THE COURT: There was some question in, I think, Mr. [23] French's mind as to whether you were also contending that they couldn't bill for a report that they dictate that is negative with an abnormality.

MR. GAGLEARD: Well, it depends which abnormality. There are a few that haven't gone through many of these, hundreds of these, thousands of these, more days that I care to think about in Borgess's storage house –

THE COURT: So there's some negative with abnormalities they can bill for and other negative with abnormalities they can't? Is that it in a nutshell?

MR. GAGLEARD: The other abnormalities deal with reflux, for example, which means the blood's going in the wrong direction, or it can mean a Baker cyst, which –

THE COURT: You are making this far too complicated. Are you saying that it is proper, in your estimation, to bill for some reports that they file that show negative with abnormality and it's not proper to bill for other negative with abnormality depending on what the abnormality is?

MR. GAGLEARD: I would say no, it's not proper to bill under either circumstance unless – unless they have, with respect to the venous study, pictures of the abnormality that they can objectively make a determination whether it's there and, if so, to what extent potentially.

THE COURT: But that's true for the negative tests. [24] If they don't look at the still photographs or view the videotape, in your view they can't bill, correct?

MR. GAGLEARD: That's right.

THE COURT: Now, if it's a negative with an abnormality, no matter what the abnormality is and no matter what the conclusion is the doctor draws, again, your position would be as to those if they don't look at the still photographs or watch the videotape of the test, they shouldn't be permitted to bill, correct?

MR. GAGLEARD: That's true.

THE COURT: Now, what about the positive tests? You haven't included those in your case. In your estimation, is it appropriate to bill for a positive finding?

MR. GAGLEARD: Yes, because the positive tests, that is, positive for a deep venous thrombosis, has objective data that accompany the work sheet, you know, that is, you've got the video and you have the photographs. You have –

THE COURT: Well, let me make this more simple because this is what I'm trying to figure out. If a doctor looks at a work sheet and that's all, is it appropriate, in your estimation, under these regulations to bill for a positive finding?

MR. GAGLEARD: Assuming that hypothetical, the answer is no because they would have no clue and they would have to accept at face value what the technician or the [25] technologist is telling them.

THE COURT: So it's your assumption, then, that in the case of positive tests, they look at the work sheet and something else before they make the positive finding, but in the case of negative or negative with abnormality, they don't look at anything else.

MR. GAGLEARD: That's right.

THE COURT: Is that it? Okay.

Is there any dispute here as to whether the physicians that submitted these bills that you are seeking recovery for looked at the work sheet?

MR. GAGLEARD: No. I'll take them at face value.

THE COURT: I want to make sure that I understand what you are relying upon in support of the claim that the doctor was required to look at something more than the work sheet before he could bill under this government program. In no particular order, we have Swafford's opinion, right?

MR. GAGLEARD: Correct.

THE COURT: We have the three affidavits you filed.

MR. GAGLEARD: Yes, sir.

THE COURT: And we have the Carrier Manual that covers something else but you argue inferentially from, right?

MR. GAGLEARD: Yes, sir.

THE COURT: Anything else?

[26] MR. GAGLEARD: Yes, sir. If you look at Dean Swafford's affidavit, you also see statements attributed to, for example, the hospital and Dr. Jain, I believe, if I am recalling Dean's affidavit correct, that would reflect that their billing practice is in fact wrong, that is, he was told to keep it in-house, people get in trouble, don't go to the outside, and that's detailed in his affidavit that was filed in opposition to the motions as initially filed, and we simply just appended it again to this.

THE COURT: Let's assume that a doctor or an administrator in one or more of these hospitals or practices thought that there was a requirement to do something more. Why does that establish that in fact

something more was required as a matter of regulation or law?

MR. GAGLEARD: Well, I think it goes to the interpretation of the words, not asking for a legal – not asking for a legal definition, not asking for a legal opinion, that is, what everybody thought what was appropriate at the time.

– THE COURT: Now, Mr. Gagleard, if there were a bunch of affidavits filed by administrators that thought it was not necessary to do anything more than look at the work sheet, you would not consider that competent evidence as to what was or was not required, would you?

MR. GAGLEARD: Well, I would – I would say that [27] there is a difference – there is a difference as to who is saying what and –

THE COURT: Well, yeah. In one case it supports you and in the other it doesn't in my example.

MR. GAGLEARD: Right. And I'm not saying that because of that fact that we're right as a matter of law or, taking the court's example, that we are wrong as a matter of law. It is but yet one more item, so to speak, that is put into the mix.

THE COURT: Okay. So we've got Swafford's opinion, the affiant's Carrier Manual on another test, and the opinion of hospital administrators reflected in Swafford's affidavit. Is that it?

MR. GAGLEARD: That's true.

THE COURT: Is there anything else?

MR. GAGLEARD: That's true. You also have, if I'm recalling correctly, you also have the Provider Manual as well.

THE COURT: I thought there was general agreement that the Provider Manual didn't speak to this issue.

MR. GAGLEARD: Well, I believe that there was one part of that where they do speak to it, and let me see if I can find it in my notes real quick.

THE COURT: As to these tests or a different kind of test? I thought you clearly admitted in your pleadings that [28] there was no regulation in the Provider Manual that spelled out what the physician had to do in connection with billing for this service.

MR. GAGLEARD: Well, I think what we said is that there is nothing that says vascular surgeons – there is nothing that says specifically that you would consider to be a definition of the word "interpret," but I think when you look at this case as a whole, in a totality, the rules, whether they're in the Provider Manual or the Carrier Manual, clearly indicate that the technical component is nothing more than the running of the test.

THE COURT: Mr. Gagleard, I'm not asking for you to wave your arms or make an argument of some inference here or there. I just want to know what you are referring to that sets forth the requirement that you say exists.

Now, I thought that I understood you in your pleadings to agree that there was no such requirement in the Provider Manual but that there are what you believe to be

requirements in other sources, so all we're talking about right now, and then you can argue when I'm done about anything you want, is whether there's something in the Provider Manual that says that they have to do something more than looking at the work sheet.

MR. GAGLEARD: When you look at HCFA's response to Dr. Jain's – Dr. Jain's FOI request, you'll see that they [29] quote from the Provider Manual and you'll see that they indicate that the technical component does not require the expertise of a doctor and is only the actual performance of the test. That's per the Provider Handbook. So when you look at the Provider Handbook and you look at the regs, whether they're in the Provider Handbook or the Carriers Manual or in any of the bulletins, to believe that the word "interpret" means looking at what the technician writes, you know, on a work sheet, and to the extent that the technician or technologist doesn't address any or all of the five factors, whether the factors are positive or negative in particular, and then the physician assumes that, one, the protocol was followed in terms of the study being properly performed and, two, that the protocol was followed, that any and all of the five factors are negative, that's what we're really dealing with here.

THE COURT: Mr. Gagleard, this is not that hard a question to answer, and I'm going to try it one last time, and if you won't answer it, then I'm going to assume that there is nothing in the regulation that's provided to the physicians that makes such a requirement. You quote extensively from the Carrier Manual. You quote from cases. I don't see anything that you quote from that Provider Manual that says that they had to look at the

still photos or look at the video. Now, I understand you are making arguments about this means that, but [30] I don't see any reference to a portion of the Provider Manual that says that they were required to do what you were requiring to do. Am I right about that or am I wrong?

MR. GAGLEARD: I believe you are accurate. There is nothing that says that the radiologist – strike that. There's nothing that says that you have to look at the video or the photos.

THE COURT: Now, I was also curious about these affidavits that you filed, and without getting to the question of whether the affidavits should or should not be stricken, which is requested in at least one of these pleadings, I don't see any discussion of any standard of care that applies to vascular surgeons in two out of the three affidavits. Is that correct?

MR. GAGLEARD: I believe that's right.

THE COURT: Why don't they speak to the standard of care if its so clear that vascular surgeons were required to do this?

MR. GAGLEARD: Because the one affidavit is from a technologist, Frank West, and the other –

THE COURT: Well, so is Mr. Swafford. He is a technologist too. That doesn't stop him from expressing an opinion.

MR. GAGLEARD: He doesn't talk about the standard of care, Your Honor.

[31] THE COURT: Okay. So we are talking about standard of care versus an opinion on the regulations, right?

MR. GAGLEARD: Yes.

THE COURT: All right. So one of them is a technician.

MR. GAGLEARD: Technologist, Frank West, the former head of the certification group.

THE COURT: All right.

MR. GAGLEARD: The other is Dr. Schwartz, a vascular surgeon.

THE COURT: Why doesn't Dr. Schwartz opine what the standard of care is if this is so clear?

MR. GAGLEARD: I believe he indicates what is appropriate and not. I intentionally stayed away from, and I assume he did too, the words "standard of care." I'm not convinced that the standard of care is pertinent. However –

THE COURT: That may be your – so your answer is it doesn't matter?

MR. GAGLEARD: That's right.

THE COURT: Okay. Now, the third affidavit does speak to the standard of care, and what the defendants respond to is that that doctor apparently has not been a treating physician for some 15 years. Is that correct?

MR. GAGLEARD: He has a physical problem which keeps him out of the operating room.

[32] THE COURT: Is it correct that the third doctor who does offer an opinion as to the standard of care has not been a treating physician for 15 years? Yes? No?

MR. GAGLEARD: He works and he's active in the practice.

THE COURT: Is he a treating physician? Yes or no?

MR. GAGLEARD: I believe he is. He works at an office and I've contacted him there, and by the way Your Honor –

THE COURT: So you disagree –

MR. GAGLEARD: I'm sorry.

THE COURT: Keep it up and we're over, understand? You came in here 20 minutes late without calling, which doesn't start you off very well, and now you insist on trying to reformulate my questions and answer something else because apparently you think I'm stupid and that I'm going to miss that, and that is not working well so far. Do you understand?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, the third doctor does opine as to the standard of care, and the defendants say I shouldn't look at that anyway because he hasn't treated patients for 15 years. Now, you believe that's incorrect, he does treat patients, rights?

MR. GAGLEARD: He does treat patients. He just [33] doesn't sit at home.

THE COURT: Doesn't what?

MR. GAGLEARD: Sit at home.

THE COURT: Which affidavit by number, if you remember right, is the third affidavit?

MR. GAGLEARD: If I understand the question correct, I would believe that that's Dr. Schwartz. That would be tab 22.

THE COURT: You describe Schwartz as the one that doesn't speak to the standard of care.

MR. GAGLEARD: Well, I say here in paragraph 7, In my opinion it is both the standard of care, and essential, that a qualified physician either personally perform the ultrasound, and then I basically go on and indicate that the physician – or he indicates, rather, that the physician should look at the underlying hard copy data.

THE COURT: Mr. Gagleard, I've read the affidavits and I've compared them, and one of the physicians refers to the standard of care and the other doesn't. I'm just simply trying to figure out which is which.

MR. GAGLEARD: That would be Dr. Schwartz, page 4, paragraph 7.

THE COURT: So when you said before that Dr. Schwartz didn't speak to the standard of care, you meant Dr. Clarkson, right?

[34] MR. GAGLEARD: No, Mr. Clarkson is not a physician, Your Honor. He is a former HCFA employee.

THE COURT: He's the technologist?

MR. GAGLEARD: No. Frank West is the technologist.

THE COURT: Okay. So the ones that don't speak to the standard of care are West and Clarkson.

MR. GAGLEARD: I believe that's right.

THE COURT: Neither of whom are doctors.

MR. GAGLEARD: That's right.

THE COURT: All right. So the only doctor, then that we have is Dr. Schwartz, and he does in paragraph 7 speak to the standard of care, correct?

MR. GAGLEARD: Yes, he does.

THE COURT: Now, what has he been doing these last 15 years, then, that the defendants, for whatever reason, seem to think means he hasn't been practicing?

MR. GAGLEARD: I think they just looked at his CV and decided that he was not working.

THE COURT: Well, the last thing that I can find that he's done that's shown in his curriculum vitae listed through December of 1985.

MR. GAGLEARD: No, sir. My – I'm sorry.

THE COURT: I'm just looking at paragraph 4 and 5 of the section of his vitae attached to the affidavit under Work Experience, and he was last in private practice in 1979 and he [35] was last with General and Vascular Surgery in December of '85. What do you understand he's done since he was with General and Vascular Surgery in 1985?

MR. GAGLEARD: Well, I'll read from paragraph 1, his affidavit: In part, I have been interpreting venous ultrasound studies and billing therefore, including Medicare/Medicaid patients over the years inclusive 1991 to date, so – and then he also says –

THE COURT: Who did he work for?

MR. GAGLEARD: I don't have that off the top of my head, Your Honor. I'm sorry.

THE COURT: I mean, there are some other groups that he lists under previous positions without any dates attached to them. Where do you contact this guy?

MR. GAGLEARD: At his office.

THE COURT: Which is located where?

MR. GAGLEARD: In the Toledo area.

THE COURT: Well, there are two – how do they answer the phone when you contact him?

MR. GAGLEARD: It's a physicians' office.

THE COURT: They say just "physicans' office"?

MR. GAGLEARD: I forgot the name of the office, Your Honor.

THE COURT: Is it Vascular Surgery of Northwestern Ohio?

[36] MR. GAGLEARD: I don't believe so.

THE COURT: Is it The Syldrum Medical Group?

MR. GAGLEARD: Your Honor, I don't want to give you inaccurate information, and to be perfectly

blunt, I've called him down there a few times, and it's just slipped my mind how they answer the phone, but it's a physicians group. I don't believe, in all fairness, that it's a vascular surgical group.

THE COURT: But he is with a group?

MR. GAGLEARD: Yes, sir.

THE COURT: And you don't know the name.

MR. GAGLEARD: I forgot the name. Totally slipped my mind.

THE COURT: The other thing that I thought was interesting about Dr. Schwartz's affidavit is that at no point does he say what he does. He says what his opinion is in terms of a doctor being permitted to bill for these, but he doesn't, for example, say I always read these studies or I sometimes read these studies or I never look at the work sheet by itself. I mean, don't you find that kind of curious inasmuch as that's the heart of this case?

MR. GAGLEARD: No, because he would have a difficult time saying the standard of care is to look at and then not view the video. If asked, he would say, I view the video.

THE COURT: Now, how does looking at a still [37] photograph tell you that a venous study was properly performed and that the information the technologist put on the work sheet was accurately recorded?

MR. GAGLEARD: Because if the study is not properly performed, you may tell from the color, that is, if the – if the Doppler was not – was not properly positioned, that may affect the color and probably would

affect the color. If there is a photograph, you would seen an obstruction. You would see the clot. That's presumably why they're taking the photograph. So when you have a positive study and you look at the photograph, giving the doctors the benefit of the doubt that, A, they're looking at the photograph and, B, the photograph is diagnostic, then the physician would see that there would be an abnormality.

THE COURT: Now I'm really confused because my understanding was that you look at these four characteristics of the veins and the responses that the veins exhibit to certain manipulations that you employ, and depending on how the veins respond to compression and other things, that collectively tells the doctor whether there is one of these DVT conditions, correct?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, you are saying that if a still photo then shows a clot –

MR. GAGLEARD: It would show an obstruction.

[38] THE COURT: Well, why do they test these four different things if every picture shows whether there is or is not a clot? Doesn't make any sense.

MR. GAGLEARD: Well, no. That's the point. If you look at the photograph and there is an obstruction, the photograph is taken to depict the obstruction. If a photograph was taken, a series of photographs – by the way, it's not just one photograph relative to a negative study, let's say, but there are a series of photographs that are taken, representative photographs that were taken,

and you would not see, based on those photographs, evidence of obstruction in a study that's been reported as negative.

THE COURT: So you're not going to see the obstruction; you're going to see the responses to the manipulation that the technician sees from which ultimately a conclusion is drawn as to whether there is or is not an obstruction. Is that a better way to phrase it?

MR. GAGLEARD: Probably. You would see an objective basis relative to that obstruction.

THE COURT: All right. You're going to see what the technician then presumably recorded on the work sheet.

MR. GAGLEARD: Yes, sir. So that you could make, you meaning the doctor, could make an independent judgment whether what the technician reported was in fact occurring.

THE COURT: All right. I think those are all of the [39] questions that I had. Anything else you want to tell me?

MR. GAGLEARD: Well, I don't think that this is an issue of scientific judgment. I think that this is not an issue, would you be better off performing the test in another way, like the *Luckey*, case, or are you better off performing an additional study to give you the same information. The issue in this case is as a matter of law do the defendants carry the day by saying the work sheet is the result of the study. It's not a legal issue. It's not a legal conclusion – or not calling for a legal conclusion but,

rather, whether the work sheet itself is the, quote, result of the study.

Now, it seems to me, as is evidenced through the various documents and materials we've given you both from the Providers Handbook and the Carriers Handbook and the bulletins, that the result of the study is not the work sheet but it's the result of the study itself, that is, the hard copy data underlying the study, whether you want to call it a video or whether you want to call it a photograph. Their whole claim is that the work sheet is the result of the study, and there's nothing that says that their client has to do anything other than look at the technician's work sheet and assume that if one or more of the factors are not addressed in the work sheet, that the study was conducted according to protocol and further assume that any or all of those factors are negative.

[40] THE COURT: Would it be appropriate for the doctor to bill if the doctor looked at the work sheet and the series of still photographs?

MR. GAGLEARD: Yes.

THE COURT: Now, why is the work sheet any different than the still photographs in terms of your conclusion that the work sheet is not the or even a result of the study?

MR. GAGLEARD: Because the work sheet is not the objective basis from which the doctor can make an independent judgment one way or the other as to whether – what the technician is reporting is accurate.

THE COURT: Well, it seems to me when you get into that argument you are making what really is a

multifaceted argument. One is that the doctors are acting improperly in charging for this service to the government, but if it's improper for the doctors to draw a conclusion looking only at the work sheet, are you not essentially contending that they've all committed malpractice, then, anytime that it turns out their ultimate conclusion was wrong because they relied only on the work sheet?

MR. GAGLEARD: Let's put it this way. I would love to be the plaintiff's lawyer in that type of case for the doctor to get up on the witness stand and say, I never looked at the study, never looked at the photos or there are were no photos, and I never looked at the video, and I have a [41] technician's work sheet that was reported negative for DVT, and, oh, by the way, the patient threw a clot two days later.

THE COURT: I didn't ask you whether you'd like to handle one of these cases. I asked you whether essentially you are saying that all of the vascular surgeons in this town were committing malpractice when they looked only at the work sheet.

MR. GAGLEARD: I would say yes.

THE COURT: Does it strike you as odd that you had to go to Ohio to find a doctor that would say that, whose vitae at least suggests he hasn't practiced since 1985?

MR. GAGLEARD: No.

THE COURT: Why is that if this is so clear-cut, in your opinion?

MR. GAGLEARD: Because, doing a fair amount of medical malpractice work myself, not a lot but a fair amount, I can tell you that it's very difficult, especially in a specialty like vascular surgery, to obtain a local expert, and that's especially true – maybe to digress a little bit, but it's very difficult, if not darn near impossible, to get somebody from U of M to testify on behalf of a plaintiff in a medical malpractice case, and I would say essentially the same thing down at the medical center inclusive of Wayne State.

THE COURT: All right.

MR. GAGLEARD: So that issue, I think, with all due [42] respect, is a nonissue in terms of the location of Dr. Schwartz.

THE COURT: I understand your argument.

MR. GAGLEARD: So they then make that assumption and then they go so far as to argue in their brief that they're performing a service because they can imagine what the veins must have looked like when they're not addressed and they don't look at anything.

We also have the survey where 10 different institutions from a variety of places all indicated that you've got to have one or the other even for a negative study. You've got to have video and at least a doctor has to look at the prints.

THE COURT: You are surely not suggesting that what Swafford says in an affidavit he was told by other hospitals is competent evidence for this purpose, are you?

MR. GAGLEARD: Well, yes, I am.

THE COURT: It's either hearsay or it's not hearsay because it's not offered for the truth of the matter asserted, and if it's not offered for the truth of the matter asserted, then it's irrelevant.

MR. GAGLEARD: It was provided to Borgess, a defendant, and Borgess acted on it. Borgess changed –

THE COURT: Why does that make it any less hearsay?

MR. GAGLEARD: Because they're a defendant and it's [43] an admission.

THE COURT: Whether they changed their procedure does not seem to be disputed here. There is no admission that they changed it because of what Swafford learned in his study, but even if you assume that they did, why does that make what he was told by 10 other hospital representatives anything other than hearsay?

MR. GAGLEARD: Because the hearsay is he was told by these other institutions, 10 of them, that they either have the video and/or they have the prints, even for a negative study.

THE COURT: Right.

MR. GAGLEARD: The issue before was Borgess said, No, no, no, we don't need the prints for the negative study. The doctors can – I'm sorry. Oh, okay.

THE COURT: I wasn't asking anything.

MR. GAGLEARD: All right. We don't need the prints for the negative study, and the dispute that Dean was embroiled in for this period of time, for a rather long

period of time, was the technicians are providing a work sheet, and when the study is negative, the doctors don't look at the video, they don't look at any hard copy data, and all they're doing is looking at the work sheet. The hospital said, Okay, do this survey, and see what other institutions around are doing or what their practice is – excuse me – relative to [44] negative studies, negative venous ultrasound studies, whether they also have prints that are provided to the doctor, even for a negative study, which provides the doctor with an objective basis from which to make a decision and to make an interpretation. After they got the results of the study, the hospital, through the vascular panel, whom I believe was headed by defendant Dr. Collins, approved and incorporated the change.

THE COURT: This is a simple question that either you are missing or I'm missing. How does what Mr. Swafford was told by other hospitals not fall squarely within the hearsay rule?

MR. GAGLEARD: For two reasons. One, he was an agent of Borgess Hospital at the time. Two –

THE COURT: That means what he said would not be hearsay. What somebody says to him is still squarely hearsay –

MR. GAGLEARD: I agree.

THE COURT: – unless you've got a new reading of 801.

MR. GAGLEARD: No, sir, I don't believe I do. No.

THE COURT: So the fact that they were told to an agent of the hospital doesn't make them any less hearsay, so what's your second attempt at making this not be hearsay?

MR. GAGLEARD: The hospital acted on not only what [45] Mr. Swafford told them, but I believe there was at least one other tech, I think Kristin Mohney, if memory serves me right, that provided the same information.

THE COURT: Mr. Gagleard, if that's your whole answer, I would suggest that if this case goes to trial, you probably better research that because it's not coming in through Mr. Swafford. It's hearsay. It's being offered for the truth of the matter asserted. It does not fall within any exception that I am aware of and it does not fall within any exception that you've cited to me, so move on.

MR. GAGLEARD: Okay. By the way, it still might come in under state of mind –

THE COURT: Move on.

MR. GAGLEARD: All right. I spend a fair amount of time in the brief indicating to the court why it's important that the doctor review the objective data underlying the study.

THE COURT: Let's concede that it's important. Let's concede they should have. The question is whether, having failed to do so, they violated the False Claims Act. The False Claims Act doesn't set forth a standard of medical practice. It sets forth a standard people have to meet in order to get money from the government.

MR. GAGLEARD: I agree.

THE COURT: Let's assume the better practice was to [46] look at the stills and/or the video. That seems like a logical assumption to make if the hospital changed their practices or their protocols in 1997 to so require. Now, what makes the failure to have done so false when bills were submitted?

MR. GAGLEARD: If you look at the 26 Modifier, if you look at what the technical component is, when you look at what a professional component is, and when you look at the various HCFA, whether you call them in the Carriers Manual or the Providers Manual, you come away with that the doctor has to provide a discrete, identifiable service, and for the doctors to win this case they have – certainly to win this motion they have to convince you that as a matter of law there was – a reasonable interpretation is that a result of the study means the technician's work sheet. That is a result of the study.

THE COURT: You're wandering all around what the issue is here, it seems to me. Whether they performed a discrete, identifiable service, it seems to me, is easy. They did perform a discrete, identifiable service. They looked at the work sheet.

Now, the only reason that summary judgment wasn't granted earlier was the hospitals were simply unwilling to answer what seemed to be a simple question, and that is what did they do. Now we know what they did. I'm not worried for [47] purposes of this ruling about whether in some instances they actually did look at the still photos and the charts and/or the video because I

don't understand those instances to come within what you contend are false claims to start with, correct?

MR. GAGLEARD: Correct.

THE COURT: You are only saying the claims were false if they didn't look at anything else, if they just looked at the work sheet, right?

MR. GAGLEARD: That's true.

THE COURT: Now, if they hadn't done anything at all, then it would seem to me that's a simple case for you; you win. Here they did perform a discrete, identifiable service; they looked at the work sheet. Now, whether that was sufficient for billing purposes under the regulations then becomes the question. We know what they did. The question is was that enough to justify billing. Do you disagree with that analysis?

MR. GAGLEARD: No, but let me add one more thing. You have to add the words without the interposition of the judgment of a third person.

THE COURT: Well, that is one of the reasons why, then, the question is whether that function in fact comports with the regulations for billing purposes, correct?

MR. GAGLEARD: Yes, sir. And what we're saying is, [48] contrary to what the defendants are saying – the defendants are saying this is a binary study, meaning it's either positive or negative, it's all objective, and so on and so forth. We are disagreeing with that. We're saying that when you perform the five maneuvers, whether it's compressibility, augmentation, so on and so forth, that

the physician is the one who needs to look at the objective data to make that determination. Otherwise, it's the technician or the technologist that is in fact making that judgment.

Now, at the depositions – I'm sure you read them, but there was a lot of quibbling about, well, is it a technician which is rendering a reading or is the technician rendering an interpretation, and there was a lot of discussion about that. The fact of the matter is the technician is rendering an interpretation. They can call it a reading, they can call it whatever fancy word they want to use, but it's still an interpretation. When the doctor looks at the work sheet, the doctor has – is believing that the technician found all these different things and interpreted all these different things and is assuming that they're accurate. The doctor has no objective basis whatsoever to draw his or her own conclusions. By definition, the doctor has to accept and is accepting what the technician writes, and I believe that when you look at the Provider Handbook, and I believe it's our Exhibit 20, under Technical Component it says, does not [49] require the expertise of a physician, and that's exactly what the doctors have put the technicians in. They put them in a position of having to make an interpretation of what the ultrasound study shows one way or the other.

I don't know if Your Honor – I don't know if Your Honor has any questions, but let me just –

THE COURT: I do have one other question. I was just flipping back through your 30 pages of your brief while you were pausing to see if you had found any case under the False Claims Act where a doctor had

actually done something and billed for it but then was held liable under the False Claims Act based upon an argument that that particular service wasn't sufficient or didn't go far enough or didn't employ the proper medical – didn't meet what the False Claims Act claimant contended was required by the standard of practice. I don't find any case of all of the cases that have come down under the False Claims Act that you rely upon in connection with these claims. Am I missing something here?

MR. GAGLEARD: I don't believe you are.

THE COURT: So it's clear, you found no case where the doctor actually did perform a service where the doctor was found liable under the False Claims Act because it was held that the nature of the service didn't comport with regulations.

MR. GAGLEARD: I don't recall any, Your Honor.

[50] THE COURT: All right. That's helpful. Thank you.

MR. GAGLEARD: Thank you. Lastly, I would say a venous ultrasound study is a radiographic – a radiology study. What the defendants are saying is that they could perform – they can do what they do, and that's fine, but a radiologist couldn't. A radiologist would have a problem in filing a false claim because they claim that a number of the discussions and comments under the various sections that we cited are directed towards the radiologist and not them. So now you almost have – not almost, you do. You have a two-tiered system. You have the same act. One is performed by a vascular surgeon.

According to the defendants, that's okay, not a false claim. You have the same act performed by a radiologist, and that would be a false claim.

THE COURT: Well, my assumption has been that the discussion about radiology services has probably been prompted by the fact that, if I remember right, I asked about how what happened in the case of these venous studies compares with radiology in, I believe, the very first Rule 16 conference that we held off the record in this case. My understanding is that in order to bill for a radiologist's services, the radiologist has to actually look at the x-rays, correct?

MR. GAGLEARD: That's it. Yes, sir.

THE COURT: Now, the regulations require the radiologist to look at the x-rays, do they not?

[51] MR. GAGLEARD: As well as the venous ultrasound, that's right.

THE COURT: The regulations do not say that you have to look at the venous ultrasound or the still photos. I understand what your argument is that they should be interpreted to require, but they don't say that.

Now, the regulations themselves say you have to look at the x-ray to bill for radiology services, do they not?

MR. GAGLEARD: I believe they do, as well as –

THE COURT: Now, am I correct in assuming that in the field of radiology apparently there is not a practice, and whether it's good or bad we will put aside for a moment, of radiologists using technicians to fill out

work sheets that put down what the technologist sees when the x-ray is taken? Would that be correct?

MR. GAGLEARD: I don't know that that's entirely accurate, Your Honor.

THE COURT: Well, do – that wasn't my most articulate question. Obviously, there are technicians that actually use the x-ray machine to take the x-ray pictures, correct?

MR. GAGLEARD: Of course.

THE COURT: If we assume that they're called x-ray technicians, just like these folks here are called venous technicians –

[52] MR. GAGLEARD: Vascular.

THE COURT: – vascular technicians, is there a practice where radiology technicians prepare a work sheet that in any way describes what's on the x-ray?

MR. GAGLEARD: There are work sheets that are in fact provided.

THE COURT: What do the work sheets say or show? Do you know?

MR. GAGLEARD: It will show what the film was. It will provide maybe some historical data.

THE COURT: I understand there must be something that accompanies the x-ray film itself that at a minimum says whose body part was being x-rayed, when it was taken, probably something about the x-ray machine and how the exposures were taken and the name of the technologist. Would that be a correct assumption?

MR. GAGLEARD: Yes, sir.

THE COURT: Now, is there anything on an x-ray technologist's sheet that's similar to the four or five findings that a venous technician – or vascular technician puts on the work sheets that the doctors in this case looked at?

MR. GAGLEARD: My understanding is yes. My understanding, I believe at Borgess, is that the answer is yes.

[53] THE COURT: At least that hospital uses a similar technique in connection with –

MR. GAGLEARD: That's my understanding.

THE COURT: Now, what you are really arguing here, are you not, is that because one or more of these manuals required x-ray – that required radiologists to do more than look at the x-ray technicians' work sheets and they had to actually look at the x-ray themselves, that therefore vascular surgeons were required to do that in connection with vascular studies?

MR. GAGLEARD: That's certainly one of the reasons and bases, that's correct, Your Honor.

THE COURT: All right. I got it. So it's clear, then, that in drafting these regulations, if HCFA or whoever drafts these things wanted to require the doctor to perform a certain specific task in order to justify billing for vascular services, they knew how to do it as illustrated by how they drafted the regulations in connection with radiology services, correct?

MR. GAGLEARD: I would argue that it's the same. I would argue –

THE COURT: I know you would argue that, but the language is clearly not the same in the regulations, correct?

MR. GAGLEARD: And I think Your Honor is assuming that the venous ultrasound study, when it's interpreted by a [54] vascular surgeon, is not a radiographic or radiology study. I'm saying it's a radiology study, and certainly as such, according to their position, it's okay.

THE COURT: Is it billed under the same code as a radiology study?

MR. GAGLEARD: Sometimes it is and sometimes it's not.

THE COURT: So a vascular surgeon gets the same fee for whatever they do, whether they read the work sheet or whether, as you contend they were required to do, they actually look at the videotape, they get the same fee as a radiologist gets for reading an x-ray?

MR. GAGLEARD: An x-ray or reading the same venous ultrasound study?

THE COURT: No. I'm asking about x-rays.

MR. GAGLEARD: I can't – I can't give you a definitive answer to that question, Your Honor.

THE COURT: So we don't know if it comes under the same regulation. I mean, in terms of that answer you don't know, right?

MR. GAGLEARD: That's true.

THE COURT: Okay. Anything else you want to tell me?

MR. GAGLEARD: I think that's it, Your Honor.

THE COURT: Any quick response? It seems to me [55] we've covered the waterfront here. Mr. Smith?

MR. SMITH: Unless the court has any questions, I have nothing to add.

THE COURT: Mr. French?

MR. FRENCH: Nothing to add. Thank you.

THE COURT: Mr. Lloyd?

MR. LLOYD: Nothing, Your Honor.

THE COURT: All right. Interesting question. I think we've finally now gotten down to the bottom of what the vascular surgeons actually do and the basis upon the plaintiff's contention that they didn't do enough to justify the billing. The court will go back and look at this matter one more time in light of the arguments here this afternoon and the answers to the court's questions and take the matter under advisement pending a written opinion.

I appreciate the excellent extensive briefs and your answers to the court's questions here this afternoon. Thank you very much.

(Proceedings concluded at 3:17 P.M.)

[56] REPORTER'S CERTIFICATE

I, Sharon E. Fox, Official Court Reporter for the United States District Court for the Western District of Michigan, appointed pursuant to the provisions of Title 28, United States Code, Section 753, do hereby certify that on the date hereinbefore set forth I reported stenographically the proceedings had in the within-entitled and numbered cause; and I do further certify that the proceedings were transcribed by me with the use of computer-aided transcription under my direction and supervision and that the foregoing is a full, true, and accurate transcript of my original stenotype notes.

/s/ Sharon E. Fox
Sharon E. Fox (CSR-3342)
U.S. District Court Reporter
315 West Allegan Avenue
Lansing, MI 48933